REMARKS

The Applicants would like to thank Examiner Sheikh for her time and courtesy in discussing the Office Action mailed on July 20, 2004 with their attorney on October 4, 7 and 12, 2004.

Claims 1-3, 5-15, 17 and 18 are pending in the present application and have been rejected in the Office Action. After carefully considering the bases for the rejections, the Applicants have amended the claims and respond to the rejections as follows:

Claim Rejections - 35 USC § 103

Claims 1-3, 5-12, 15 and 17 have been rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,042,849 to Richardson et al. ("Richardson" or "the `849 patent"), either alone or in combination with U.S. Patent No. 6,258,846 to Hermelin et al. ("Hermelin" or "the `846 patent").

Richardson discloses a pharmaceutical preparation containing ionic magnesium combined with additional therapeutic substances for the treatment and control of vasoconstriction and related conditions. Pages 5-6 of the Office Action state:

> While Richardson et al. teach delayed release, enterically-coated magnesium compounds that are delivered to the small intestine or post-gastric environment, Richardson et al. do not explicitly state that the calcium/calcium salts are provided in an immediate release form. However, based on the teachings of Richardson et al., that the tablet components are divided into two portions, one fully released into the stomach and the other portion released only in the intestine, whereby magnesium is taught to be released in the intestine, **one of ordinary skill in the art could conclude that the remaining calcium or calcium salts could be formulated for immediate release to**

> **provide complete release of calcium in the stomach**, since magnesium is taught for release in the intestine.
>
> (Emphasis added.)

The Applicants respectfully disagree with this statement and submit that, based on the disclosure by Richardson et al., one of ordinary skill in the art would not find that the `849 patent teaches a composition that immediately releases calcium in the stomach and delays the release of magnesium until it reaches the intestine. Richardson teaches magnesium formulations where magnesium is the primary component. "Magnesium is formulated in combination with vitamin E, vitamin C, folate, selenium, and optionally melatonin." Abstract. Richardson et al. disclose that other substances can be combined with the magnesium, but leave no doubt that these additional components are added to a magnesium formulation. The Richardson patent states at col. 3, lines 9-15 that:

> The present invention resides in a pharmaceutical preparation for use as an oral dosage form. The preparation contains ionic magnesium **combined with additional therapeutic substances** in an interactive and complementary manner for the treatment and control of vasoconstriction and of the physiological conditions that give rise to vasoconstriction.
>
> (Emphasis added.)

One of the "additional therapeutic substances" that is combined with magnesium is calcium, which Richardson describes as being "optionally" included in magnesium formulations.

> Additional active agents are **optionally** included in the formulations of this invention for the treatment of specific conditions or for use in specific patient populations. Examples are calcium and calcium salts (about 400 mg to about 1200 mg).
>
> Col. 7, lines 62-66. (Emphasis added.)

Moreover, Richardson describes the amounts of the other components in the formulations "relative to magnesium." At col. 6, lines 34-42, describes "Compositions, Formulations and Dosages" of the invention as follows:

> The amounts of the individual components of the pharmaceutical preparation of this invention can vary, although in preferred preparations the components are present in amounts lying within certain ranges. Expressed both in terms of milligrams and in terms of weight ratios relative to atomic magnesium, the components and their preferred ranges are as follows:

Table 1 lists the basic formulations taught by Richardson, all of which are predominantly composed of magnesium. The right hand column of Table 1 lists the amounts of the other ingredients in the formulation under the heading, "Ranges in Weight Ratios Relative to Magnesium." One skilled in the art could only interpret this to mean that Richardson required all of the formulations to include magnesium. Therefore, the statement in the Office Action that "one of ordinary skill in the art could conclude" that one portion of a two portion tablet could contain a calcium compound in the absence of magnesium and the second portion could contain magnesium is contrary to Richardson's teachings.

Furthermore, Richardson discloses a two layer tablet at col. 9, lines 34-54 and in Example 2. In both cases, the two layer tablets have first and second layers that are predominantly formed from magnesium compounds. Richardson does not teach that calcium compounds are present in either layer of the two layer tablets. Therefore, there is no teaching or suggestion in Richardson that would lead one of ordinary skill in the art to conclude that a two layer tablet could have a calcium compound with no magnesium in one layer and a magnesium compound in the other layer.

The Office Action states at page 7 that Hermelin `846 patent teaches: "a nutritional supplement composition comprising a combination of calcium, provided in an immediate release form and magnesium, provided in a combined release form." The Applicants respectfully disagree with this interpretation of Hermelin and find that it relies on impermissible hindsight to cherry pick portions of the Hermelin patent to read on the pending claims.

Hermelin et al. disclose at col. 12, lines 16-34 that their compositions can include calcium and magnesium and that both components can be in either an immediate or controlled release form.

> Calcium is preferably present in the composition of the present inventive subject matter in an amount ranging from about 100 mg to about 2,500 mg. More preferably, calcium is present in an amount ranging from about 100 mg to about 1,000 mg. Even more preferably, **calcium is present in an immediate release form** in an amount ranging from about 100 mg to about 500 mg. Most preferably, **calcium is present in a controlled release form** in an amount ranging from about 500 mg to about 2,000 mg.
>
> Magnesium is preferably present in the composition of the present inventive subject matter in an amount ranging from about 25 mg to about 400 mg. More preferably, **magnesium is present** in the composition of the present inventive subject matter **in an immediate release form** in an amount ranging from about 25 mg to about 100 mg. Even more preferably, **magnesium is present** in the composition of the present inventive subject matter **in a controlled release form** in an amount ranging from about 100 mg to about 400 mg.
>
> (Emphasis added.)

Hermelin defines the terms "immediate release form" and "controlled release form" at col. 12, line 66 to col. 13, line 3 as follows:

> As used herein, a "controlled release form" means any form having at least one component formulated for controlled release. As used herein, "immediate

release form" means any form having all its components formulated for immediate release.

Hermelin et al. teach that both magnesium and calcium can be present in either an immediate release form or a controlled release form. However, there is no teaching or suggestion that magnesium and calcium are present in different forms, i.e., there is no teaching that calcium is present in an immediate release form and magnesium is present in a controlled release form. Examples 1-4 of Hamerlin teach that calcium and magnesium are released simultaneously. Moreover, there is no teaching or suggestion in Hermelin that a controlled release magnesium would not be simultaneously released with an immediate release calcium. One of ordinary skill in the art would interpret controlled release to mean that a component is released over time, not that it is delay released until passage into the intestine. If Hamerlin et al. intended for the magnesium component to be release only after reaching the intestine, they would have used the term "delay released," a term they use in other sections of their patent.

Even if Hermelin taught an immediate release calcium and a controlled release magnesium, the magnesium would start to release in the stomach and continue to release when it reached the intestine. Therefore, calcium and magnesium would be released simultaneously and the present invention which delays the release of magnesium until substantially all of the calcium compound has been released would not be obvious in view of the Hermelin patent. Moreover, there is no teaching or suggestion in the Hermelin patent which would lead one of ordinary skill in the art to release substantially all of the calcium component before beginning to release the magnesium component.

Claims 13, 14 and 18 have been rejected under 35 U.S.C. 103(a) as being unpatentable over the `849 Richardson patent as applied to claims 1-3, 5-12, 15 and 17, and further in view of the Hermelin `846 patent. The Office Action states at pages 7-8 that Richardson discloses a formulation with a delay release of both magnesium and calcium in the intestine.

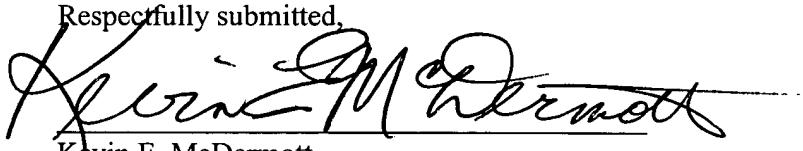
> Richardson, as discussed above, teaches an oral pharmaceutical composition comprising a dual layer combination tablet which is divided into two portions, **one that is fully released into the stomach upon ingestion**, and the other protected by an acid-resistant coating for release only in the intestine, whereby the intestine-release portion contains magnesium compounds/magnesium salts in combination with additional active agents and therapeutic substances, such as calcium and calcium salts.
>
> (Emphasis added)

Richardson, either alone or in combination with Hermelin, fails to disclose the sequential release of a first component having an active ingredient consisting essentially of one or more calcium compounds and a second component having an active ingredient consisting essentially of one or more magnesium compounds and a release-controlling agent in order to avoid interaction between the two components. As discussed above, Richardson teaches dual tablets wherein both layers contain substantial amounts of magnesium and there is no teaching or suggestion of a layer containing calcium without magnesium being included. Hermelin also fails to teach a composition which releases calcium separately from magnesium, as discussed above. Moreover, there is no teaching nor suggestion in either of these references that would make the present invention obvious to one of ordinary skill in the art. There is no teaching nor suggestion in either Richardson or Hermelin of a dual tablet having an immediate release first layer that includes a calcium compound in the absence of

magnesium and a second delayed release layer that includes magnesium in the absence of calcium.

The Applicants have amended their claims to more clearly define their invention and distinguish its novel features from the prior art. Moreover, the arguments submitted herein clearly show that the prior art does not teach or suggest a formulation with an immediate release calcium component and a delayed release magnesium component. Therefore, the Applicants respectfully request that the rejections of the claims as obvious in view of the cited art be withdrawn and that the amended claims be allowed.

Respectfully submitted,



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